REMARKS

Claims 1-4 and 6-16 are pending in the instant application. As suggested by the Examiner, Applicant has amended Claim 4 to substitute the word "isolated" for the word "derived". Applicant appreciates the Examiner's attention to the priority applications and apologizes for the typographical error that occurred in the application number of one of the applications. Enclosed is a substitute oath as requested, along with a request for a corrected filing receipt.

Please note that Applicant has received a provisional double-patenting rejection over the present application in US Application Number 07/958,426, filed October 8, 1992, which is pending before the Office.

35 USC 112, second paragraph

Claims 1-4 and 6-16 were rejected under 35 USC 112, second paragraph, for allegedly being indefinite. Applicant traverses in part. Claims 1 and 6 were rejected due to the word "glycolipid" and Claim 4 was rejected due to the word "derived". As evidenced by the amendment above, Applicant has amended Claim 4 to replace the word "derived" with the word "isolated", as suggested. Therefore, Applicant believes that the rejection of Claim 4 has been overcome.

As to the rejection of Claims 1 and 6, Applicant asserts that the term "glycolipid" is a term recognized by one of skill in the art. Therefore, these claims are not indefinite. First of all, Applicant believes that there is some confusion over the Specification, on page 10, wherein the word "glycolipid" is found. The Examiner quotes from that part of the Specification, but perhaps the punctuation renders the information unclear. The relevant sentence reads in part: "...membrane proteins such as proteosomes, lipopolysaccharides, glycolipids such as gangliosides, or a variety of proteins or peptides to which hydrophobic anchors have been chemically or genetically added." The intent of this section was to list various molecules to which a hydrophobic anchor has been added, i.e., certain proteins or peptides, or molecules

which are hydrophobic moieties. Therefore, glycolipids, such as gangliosides, were a separate listing from proteins or peptides, and do not encompass proteins or peptides generally.

Secondly, glycolipids are a well-defined class of molecules, which would be appreciated by a skilled artisan and would not need to be separately defined in the Specification. One of ordinary skill in the art would appreciate that a glycolipid is "a lipid that contains one or more carbohydrate groups". [See "The American Heritage Dictionary of the English Language", Fourth Edition 2000.] Further, the International Union of Pure and Applied Chemistry and the International Union of Biochemistry and Molecular Biology has a joint commission on biochemical nomenclature. G. P. Moss in the Department of Chemistry, Queen Mary University of London, has prepared a website version of the Nomenclature of Glycolipids. [See www.chem.qmul.ac.uk/iupac/misc/glylp.html.] In the General Considerations section of the Nomenclature of Glycolipids, Moss states: "Glycolipids are glycosyl derivatives of lipids such as acylglycerols, ceramides and prenols." and in the Generic Terms section, Moss states: "The term glycolipid designates any compound containing one or more monosaccharide residues bound by a glycosidic linkage to a hydrophobic moiety such as an acylglycerol, a sphingoid, a ceramide (N-acysphingoid) or a prenyl phosphate." Applicant asserts, therefore, that one of skill in the art clearly appreciates the term "glycolipid" and it is not indefinite.

For these reasons, Applicant respectfully requests the withdrawal of the 35 USC 112, second paragraph, rejections.

35 USC 112, first paragraph

All of the pending claims have been rejected under 35 USC 112, first paragraph, as allegedly being non-enabled. Applicant respectfully traverses. It appears that the confusion surrounding the definition of "glycolipids", as discussed above, may have contributed to this rejection, since the Office Action recites on page 5: "The specification defines 'glycolipid' as 'a ganglioside or a variety of protein or peptides with hydrophobic anchors.' As a result, Applicant

reiterates the argument provided that glycolipids do not include general proteins or peptides within its definition.

The Examiner also opines on page 5 that "There are no challenge experiments provided which demonstrate the use of even a single glycolipid and a proteosome". In response to this comment, Applicant presents an article in which he is a co-author entitled "GD3/proteosome vaccines induce consistent IgM antibodies against the ganglioside GD3", *Vaccine*, 11(12):1199-1204 (1993). [A copy of this article is enclosed for the convenience of the Examiner. Please note: the priority date of this application predates the publication of the article.] As stated in the Abstract of the article: "Highly hydrophobic Neisserial outer membrane proteins (OMP) form multimolecular liposome-like vesicular structures termed proteosomes which can readily incorporate amphiphilic molecules such as GD3 gangliosides....The application of proteosomes to enhance the immune response to GD3 extends the concept of the proteosome immunopotentiating system from lipopeptides to amphipathic carbohydrate epitopes such as cell-surface gangliosides."

The authors utilized mice to exhibit the immunizing effect of the GD3/proteosome vaccines. As a result, the authors established that these vaccine formulations induced antibodies in the mice and acted as immunogens. Therefore, the combination of a glycolipid and a proteosome is an immunogenic composition or vaccine. Applicant has shown the effectiveness of a glycolipid/proteosome vaccine and therefore, respectfully requests withdrawal of the rejection under 35 USC 112, first paragraph.

Applicant asserts that the pending claims are now in condition for allowance and respectfully requests such favorable action. If the Examiner has any questions, please feel free to call the undersigned, Karen Dow, at (858) 720-7960 or send a facsimile at (858) 720-5125.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

In the unlikely event that the transmittal letter is separated from this request and the Patent Office determines that a fee is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Attorney Docket No. 406462000102. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: April 25, 2002

By: Karen Babyak Dow
Karen B. Dow
Reg. No. 29,684

Morrison & Foerster LLP
3811 Valley Centre Drive
Suite 500
San Diego, California 92130-2332
Telephone: (858) 720-7960
Facsimile: (858) 720-5125

Enclosures:
Substitute Declaration For Utility Patent Application
Request for Corrected Filing Receipt
Livingston, et al., *Vaccine* 11(12):1199-1204 (1993)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification

On page 1, under the heading "Cross-References to Related Applications, please replace the paragraph with the following:

--This application is a continuation of [a]Application No. 08/677,302, filed July 9, 1996, now U.S. Patent No. 5,985,284, which is a continuation of [a]Application No. [08/673,756] 08/637,756, filed [June 27, 1996] April 29, 1996, now U.S. Patent No. [5,858,268] 5,961,970, which is a continuation of PCT [a]Application No. PCT/US93/10402, filed October 29, 1993.--

In the Claims

Please amend the claims as follows:

Claim 4 (Thrice Amended) The immmunogenic composition of claim 1, wherein the proteosomes are [derived] isolated from *N. meningiditis*.